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Art Unit 1635

Attn: Mail Stop Amendment

Re: U.S. Utility Patent Application
Application No. 10/551,466; § 371(c) Date: August 7, 2006
For: **Conjugate for Gene Transfer Comprising Oligonucleotide and
Hydrophilic Polymer, Polyelectrolyte Complex Micelles Formed from
the Conjugate, and Methods for Preparation Thereof**
Inventors: JEONG et al.
Our Ref: 2236.0180000/JUK/SMW

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Restriction and Election of Species Requirements; and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Scott M. Woodhouse
Agent for Applicants
Registration No. 54,747

Enclosures
749053_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

JEONG *et al.*

Appl. No.: 10/551,466

§ 371(c) Date: August 7, 2006

**For: Conjugate for Gene Transfer
Comprising Oligonucleotide and
Hydrophilic Polymer,
Polyelectrolyte Complex Micelles
Formed from the Conjugate, and
Methods for Preparation Thereof**

Confirmation No.: 4435

Art Unit: 1635

Examiner: Bowman, Amy Hudson

Atty. Docket: 2236.0180000/JUK/SMW

Reply to Restriction and Election of Species Requirements

Sir:

In reply to the Office Action dated October 15, 2007, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group **I**, represented by claims 1-8. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

In addition, Applicants provisionally elect as species: (1) from claim 4, polyethylene glycol, (2) from claim 5, an acid-cleavable linkage, (3) from claim 6, a phosphodiester bond, (4) from claim 7, an antisense oligonucleotide, and (5) from claim 8, c-myc. Applicants assert the right to claim additional species in the event that a generic claim hereto is found allowable in accordance with 37 C.F.R. § 1.141(a).

Both elections are made **with** traverse. The inventions of Groups **I**, **III** and **VI** are related as subcombination-combination. The micelle of claims 11-12 (Group **III**) as well as of claims 11 and 13 (Group **IV**) require a conjugate of Group **I**. Thus, two-way distinctness has not been shown between Group **I** and each of Groups **III-IV**. Moreover,

a search of Groups **I** would inevitably cover Groups **II-IV**, and thus would not present an undue burden to the U.S.P.T.O. The burden is on the Examiner to demonstrate a *prima facie* undue burden. See, e.g., MPEP § 803.

Further, Groups **III** and **IV** both include claim 11. Restriction practice is not applicable to a single claim. See *In re Weber*, 198 U.S.P.Q. 332 (C.C.P.A. 1978) and its companion case, *In re Haas*, 198 U.S.P.Q. 334 (C.C.P.A. 1978). These cases make it clear that 35 U.S.C. § 121 does not grant to the U.S. Patent and Trademark Office (PTO) the authority to refuse to examine a single claimed invention. Section 121 only applies to *plural* claimed inventions in *different* claims, where the different claims vary not just in scope, but in the invention to which each is directed. In view of this rule, Applicants submit that the restriction between Groups **III** and **IV** are improper since both groups restrict within a single claim, i.e., claim 11. Thus, Applicant's additionally request that the Examiner reconsider the restriction between Groups **III** and **IV**, and that they be rejoined.

Additionally, the Examiner failed to include claim 14 in any of Groups **I-IV**. Applicants respectfully request that the Examiner clarify the Restriction Requirement to include claim 14.

With regards to the election of species, a reasonable number of species may be claimed when there is an allowable claim generic thereto. See, e.g., 37 CFR § 1.141 and MPEP § 806.04. In claims 4, 5, 6, 7, 8, there are only 3, 7, 4, 3 or 7 species listed. This certainly would fall within a reasonable number of species. Additionally, the members listed in claims 4-8 all have a common property and/or activity, and are disclosed as

Markush-type claims. It is well established that Markush-type claims are permitted in patent claims when they belong to an art-recognized class, such as in the present instance. See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). For example, the members listed in claim 4, i.e., polyethylene glycol, polyvinylpyrrolidone and polyoxaline, share common chemical properties as hydrophobic polymers and each member can be substituted one for the other with the expectation that the same intended result would be achieved. Thus, Applicants respectfully request the Examiner remove the requirement for an election of species from claims 4-8.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: November 15, 2007

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